



BILLING CODE 4165-15

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Solicitation of Nominations for Organizational Representatives to the Advisory Committee on Heritable Disorders in Newborns and Children

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Request for nominations.

SUMMARY: HRSA is seeking nominations from organizations to send a representative to be a liaison to the Advisory Committee on Heritable Disorders in Newborns and Children (Committee). Selections will be based on a review of the organization's subject area of expertise, mission, relevancy, and benefit provided relative to the Committee's purpose. The organizational representatives are non-voting liaisons. The Committee provides advice, recommendations, and technical information about aspects of heritable disorders and newborn and childhood screening to the Secretary of HHS. HRSA is seeking nominations of qualified organizations to fill up to three positions.

Authority: Section 1111 of the Public Health Service (PHS) Act, as amended by the Newborn Screening Saves Lives Reauthorization Act of 2014 (42 U.S.C. § 300b-10). The Committee is governed by the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. App.), and 41 CFR Part 102-3, which set forth standards for the formation and use of advisory committees.

DATES: Written nominations for organization representatives on the Committee must be received on or before January 17, 2019.

ADDRESSES: Nomination packages must be submitted electronically as email attachments to Catharine Riley, Ph.D., MPH, Genetic Services Branch, Maternal and Child Health Bureau, HRSA, criley@hrsa.gov.

FOR FURTHER INFORMATION CONTACT: Designated Federal Official (DFO)
Catharine Riley, Ph.D., MPH. Address: MCHB, HRSA 5600 Fishers Lane, Room 18-W-68, Rockville, MD 20857; phone number: 301-443-1291; email: criley@hrsa.gov. A copy of the Committee Charter and list of the current membership can be obtained by accessing the Advisory Committee website at: www.hrsa.gov/advisory-committees/heritable-disorders.

SUPPLEMENTARY INFORMATION: The Committee is chartered under section 1111 of the PHS Act, as amended by the Newborn Screening Saves Lives Reauthorization Act of 2014 (42 U.S.C. § 300b-10). The Committee was established in 2003 to advise the Secretary of HHS regarding newborn screening tests, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having or at risk for heritable disorders. In addition, the Committee provides advice and recommendations to the Secretary concerning the grants and projects authorized under section 1109 of the PHS Act and technical information to develop policies and priorities for grants, including those that will enhance the ability of the state and local health agencies to provide for newborn and child screening, counseling and health care services for newborns, and children having or at risk for heritable disorders. The Committee also is governed by the provisions of FACA, as amended (5 U.S.C. App. 2), and 41 CFR Part 102-3, which set forth standards for the formation and use of advisory committees.

The Committee reviews and reports regularly on newborn and childhood screening practices for heritable disorders, recommends improvements in the national newborn and

childhood heritable screening programs, and recommends conditions for inclusion in the Recommended Uniform Screening Panel (RUSP). The Committee's recommendations regarding additional conditions/inherited disorders for screening that have been adopted by the Secretary of HHS are included in the RUSP and constitute part of the comprehensive guidelines supported by HRSA pursuant to section 2713 of the PHS Act, codified at 42 U.S.C. § 300gg-13. Under this provision, non-grandfathered health plans and group and individual health insurance issuers are required to cover screenings included in the HRSA-supported comprehensive guidelines without charging a co-payment, co-insurance, or deductible for plan years (i.e., in the individual market, policy years) beginning on or after the date that is 1 year from the Secretary's adoption of the condition for screening.

Nominations: The Committee may invite up to 15 organizations to designate individuals to serve as non-voting liaisons. Organizations should demonstrate wide-ranging newborn screening and heritable disorders interests. In addition, the organization's work should inform the activities of the Committee. Eligible organizations must represent national public health constituencies, medical professional societies, or organizations with large, broad constituencies and broad interest or involvement in newborn screening. Organizations which represent narrow interests (e.g., interest in a single disease or treatment) or smaller constituencies are not eligible.

Organizational representatives attend Committee meetings to provide relevant expertise and perspectives to Committee members during their deliberations and discussions, but they do not vote and are not considered official members of the Committee.

Applications must contain a cover letter and statement. The cover letter should include: organization name and mission statement; contact information for the designated representative, including point of contact name, address, email, telephone number; and website of the

organization. The statement should include: perspective and expertise provided by the organization and its relevance to the Committee; a description of how the Committee's work affects and impacts the organization and its constituency; a list of organizational projects, programs, and products that are of relevance to the Committee's work; an affirmation of the organization's commitment to identify a representative with expertise who can attend Committee meetings in person and provide input to the Committee, at the discretion of the Chairperson; an affirmation of the organization's commitment to financially support (e.g., cover travel expenses) a representative to attend committee meetings held in Rockville, MD; an affirmation of the organization's commitment to ensure active contribution to and dissemination of Committee activities and recommendations to its constituencies; affirmation the designated representative is able to serve as the liaison; and an affirmation that the organization has no conflict of interest that would preclude informing the Committee in a fair and balanced manner. If there are potential conflicts of interest, please detail the information concerning any possible conflicts of interest relative to both the organization and the proposed organizational representative (e.g., current or anticipated employment, consultancies, research grants, or contracts), as well as how the organization proposes to address the potential conflict.

Organizations are eligible to send a representative as long as the organization's subject area of expertise and mission is relevant to the Committee's purpose, objective, scope of activities and duties, and as long as the organization actively participates on Committee activities. Every three years, the Chair and DFO will re-assess the organization's mission, relevancy, and benefit as it relates to the Committee's purpose, objective, scope of activities, and duties. Every three years current organizations will be asked to reaffirm their commitment to send an organizational representative.

The selection of eligible organizations is based on a review of the organization's subject area of expertise, mission, relevancy, and benefit as it relates to the Committee's purpose. The Committee Charter, legislation, and list of current voting membership may be obtained by accessing the Committee Website at <http://www.hrsa.gov/advisory-committees/heritable-disorders>. Final selection of organizational representatives will be made by the Committee Chair and HRSA.

Amy P. McNulty,

Acting Director,

Division of the Executive Secretariat.

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